

Early Single Center Experience with the Solitaire Thrombectomy Device for the Treatment of Acute Ischemic Stroke

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Summary

We report the immediate technical and clinical outcome of a new self-expanding fully retrievable stent in the treatment of acute ischemic stroke.

Eleven consecutive patients with acute intracerebral artery occlusions were treated with a self-expandable fully retrievable intracranial stent (Solitaire AB). Four patients had an occlusion of the basilar artery, five had a middle cerebral artery occlusion and two had terminal carotid artery occlusions. Recanalization results were assessed by follow-up angiography immediately after the procedure. Neurologic status was evaluated before and after treatment (90-day follow-up) according to the National Institutes of Health Stroke Scale (NIHSS) and modified Rankin scales (mRS).

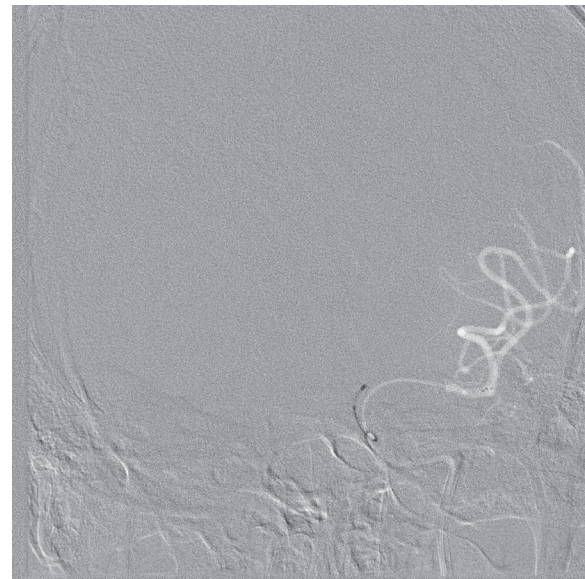
Successful revascularization (TICI 2a/b and 3) was achieved in 11 of 11 (100%) patients, a TICI 3 state was accomplished in two (18%) patients, and partial recanalization or slow distal branch filling with filling of more than two-thirds of the vessel territory (TICI 2a/2b) was achieved in nine (82%) patients. The stent was removed in all patients. The mean time from stroke symptom onset to recanalization was 339 minutes (+/- 114.3 minutes). NIHSS on admission was 16.09 (+/- 4.7). Almost two-thirds of the patients (61.2%) improved by >6 points on the NIHSS at discharge, and 30% showed a mRS of <2 at 90 days. Mortality was 9%. One patient with a BA occlusion had a massive brain stem infarction and died two days after the procedure. There were no intracranial hemorrhages.

The use of the Solitaire in ischemic stroke patients shows encouraging results. However, fur-

ther prospective large randomized trials are mandatory to confirm these early results.

Introduction

The interventional treatment of acute ischemic stroke has evolved in the past few years. The only known drug therapy for acute ischemic stroke is thrombolysis with recombinant tissue plasminogen activator or urokinase, which has been proven in many clinical trials to be effective in improving clinical outcome and reducing subsequent disability. The improvement in this therapy has been the extension of the three-hour time frame to 4.5 hours in which it can be safely administered¹⁻³. Treatment of ischemic stroke in patients with large intracranial vessel occlusion still remains a challenge because intravenous thrombolysis is often limited⁴. Several trials have shown the efficacy of a mechanical approach. These trials were able to show that a mechanical approach, alone or in combination with intravenous and intra-arterial tissue plasminogen activator or urokinase administration, could improve the recanalization rate and thereby the outcome of patients⁵⁻⁸. Recently, a new technique with the Solitaire AB/FR device (ev3, CA, USA) was introduced⁹⁻¹⁰. This stent device is placed and deployed in the occluded vessel within the thrombus formation and is then withdrawn in its unfolded state. The Solitaire FR is a new self-expanding and fully retrievable nitinol stent based on the Solitaire AB, which is commonly used for stent-assisted treatment of intracranial aneurysms⁸.



↑ Figure 2 Deployed Solitaire (arrows at the proximal and distal end of the stent) in the MCA.

← Figure 1 Acute M1 occlusion.

Table 1 Patients characteristics..

Number	Patient's ID	Age	Sex	Artery occlusion	Device	Max. retrieval maneuvers	TICI	NIHSS	NIHSS after intervention	mfR	Door to needle time
1	EE	70	w	C7	Solitaire	2	2a	11	5	2	330
2	EA	72	m	BA	Solitaire	2	2b	21	15	2	290
3	LA	54	w	M1	Solitaire	1	3	11	5	1	180
4	LF	67	w	BA	Solitaire	3	2b	17	10	2	360
5	SB	49	w	M1	Solitaire	3	2a	17	17	5	360
6	WB	82	w	BA	Solitaire	4	2b	26	26	exitus	560
7	WH	68	m	BA	Solitaire	3	2b	15	8	4	510
8	LD	28	w	M1	Solitaire	1	2b	11	6	1	270
9	BR	50	w	C7	Solitaire	1	3	16	5	2	300
10	GH	62	m	M1	Solitaire	2	2b	17	8	2	270
11	AM	46	w	M1	Solitaire	3	2a	15	7	2	300

Legend: NIHSS: National Institutes of Health Stroke Scale
mfR: modified Rankin scales.

The aim of this study is to report early single center results in patients with acute ischemic stroke that had undergone mechanical thrombectomy by the Solitaire AB thrombectomy device.

Subjects and Methods

From April 2010 to December 2010 eleven consecutive patients with acute ischemic stroke underwent stent-assisted mechanical recanalization.



Figure 3 After removal of the stent recanalized vessel (TICI 3).

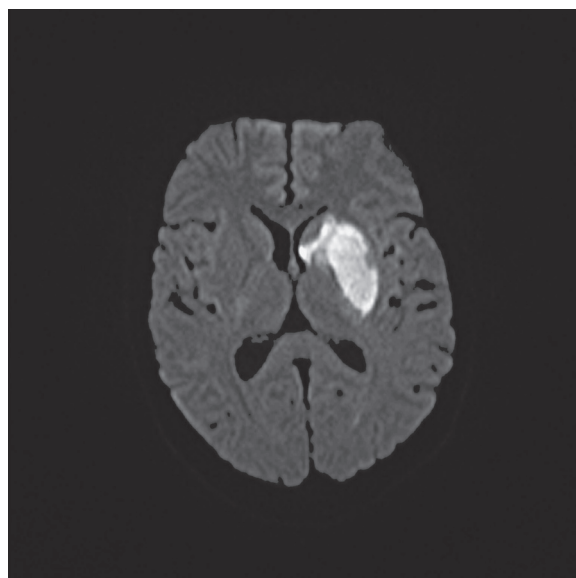


Figure 4 In the control MRI 24 hours after the procedure a diffusion positive infarct of the basal ganglia is visible, mRS 1, NIHSS 1.

zation in our department. Neurologic evaluation (NIHSS) was performed on admission, at discharge, and 30 days after therapy by an experienced stroke neurologist. The mRS was assessed by an experienced stroke neurologist at 30 and 90 days after treatment. Computed tomography (CT) and CT angiography or MRI and MRA of the intracranial vessels were performed on admission. Control CT and/or MRI scans were acquired 24 hours after treatment or before discharge, or when the patient's symptoms worsened. A mRS of 0 to 2 was defined as a good neurologic outcome; poor outcome was assumed when the mRS score was 3 to 6. Before treatment, informed consent was obtained from either the patient him/herself or in case of an extreme emergency and patients' unconsciousness and absence of a legal representative there was no informed consent obtained.

Patient selection

The main inclusion criteria were (1) patient age 18 years; (2) NIHSS score 8; (3) TICI score of 0 or 1 in an accessible vessel; (4) no detection of ICH and no marked ischemia on the CT

scan and (5) arrival at the hospital within 4.5 hours of symptom onset for the anterior circulation; the time window was extended for the posterior circulation when magnetic resonance imaging ruled out ischemic damage of the brainstem of < 50%.

When a large-vessel occlusion was found (for example, occlusion in the M1 segment of the middle cerebral artery, internal carotid artery, or basilar artery), treatment was started with intravenous tissue plasminogen activator. Patients were then transferred for interventional treatment. All the patients were treated under intubation and ventilation.

Device

The Solitaire AB (ev3, CA, USA) is a laser-cut, self-expanding, and fully retrievable split-design nitinol device. The device, which is available in several sizes ranging from 4×15 mm to 6×30 mm, is attached to a nitinol pushwire. It runs through a 0.021-in. microcatheter. Vessels from 2 to 5.5 mm in diameter can be treated. The advantage of this device is that it is a fully recoverable, self-expanding-stent device that can be used as both a temporary endovascular

bypass and a thrombectomy device. Moreover, it can be electrolytically detached like a coil in case permanent stent placement is necessary, such as in the setting of an atherothrombotic stenotic lesion.

Interventional Treatment

All procedures were performed on a biplane angiography machine (Siemens Artis Zee, Siemens Healthcare, Erlangen, Germany). After occlusion of the target vessel was verified angiographically and rated on the TICI scale, a 90 cm long, 6F guiding catheter (Chaperon, Microvention Inc, Columbia, USA) was placed either in the vertebral artery or the internal carotid artery, and intravenous lytic therapy was stopped. The target vessel was navigated with a 0.014-in. microwire (Traxcess, Microvention Inc, Columbia, USA; Syncro 2, Boston Scientific, Miami, USA) and a 0.021-in. microcatheter (Prowler plus, ev3, CA, USA). After placement of the microcatheter distal to the thrombus, as verified by intra-arterial contrast medium injection, the Solitaire device was advanced through the microcatheter. The microcatheter was then pulled back until the Solitaire was completely unfolded. The stent was given three minutes rest until it was retrieved. Afterwards, the device was pulled back in its unfolded state under continuous aspiration with a 50-mL syringe together with the microcatheter into the guiding catheter. When the subsequent control angiogram showed a TICI score <2, the procedure was repeated until a TICI score of 2 or 3 was reached. Furthermore a bolus of heparin of 5000 IE was administered intravenously and in those cases in which a TICI 2a/2b was reached, a bolus of Abciximab 10 mg was applied intra-arterially.

Discussion

The outcome of the treatment of large-vessel arterial occlusions with intravenous tissue plasminogen activator is poor ¹¹. Intra-arterial thrombolysis extends the time window for patients with middle cerebral artery occlusions up to six hours ¹². For the treatment in case of failed recanalization after thrombolysis or in patients with contraindications to thrombolytic therapy mechanical thrombectomy techniques are increasingly used. A variety of devices have been developed such as MERCI and PENUM-

BRA, but all of them showed limited results ¹³. Earlier than treating acute stroke patients with MERCI or PENUMBRA there were stents as a proper device and in the SARIS trial there was given evidence, that stent-assisted thrombectomy in acute ischemic stroke is a proper method with a good clinical outcome ¹⁴. There are two advantages suggested of stenting in acute stroke patients in the literature. First, it is not time-consuming and second it has a very high reported immediate recanalization rate ^{15,16}. But there are also disadvantages. On the one hand stent placement requires aggressive antiplatelet therapy like a combination of acetylsalicylic acid and clopidogrel (glycoprotein IIb/IIIa receptor inhibitor) ¹⁷; on the other hand the clot is still in place, it is only pressed to the vessel wall. The concerns of early re-thrombosis are evident. Last but not least, a placed stent may induce late in-stent stenosis. So the best thrombectomy device is a device that can be removed – a removable stent. The Solitaire AB is a laser-cut, self-expanding, and fully recapture able, split-design nitinol device made for stent-assisted coil embolization of aneurysms, which are characterized by a wide neck ¹⁸. Recent literature shows promising data dealing with success rate of clot removal and patients' outcome with the Solitaire thrombectomy device ¹⁹.

Our retrospective study demonstrated that deployment and withdrawal of the unfolded Solitaire stent is a safe and feasible method to achieve recanalization when treating acute ischemic stroke due to acute intracranial artery occlusion. The clinical improvement observed in the present study is lower than that reported by Roth et al. ²⁰. In our opinion, this is a matter of time. Our mean time was 339 minutes compared to 277 minutes in Roth et al.'s study. Nevertheless we achieved a comparable recanalization rate to the study of Roth et al. In our opinion, this is due to fast and effective clot removal, and the opportunity to provide flow between different retrieval attempts. Comparing our data to different data in the literature such as the MERCI, Multi MERCI, and Penumbra trials the opportunity to provide flow between different retrieval attempts is impossible with these devices. This fact might explain why the MERCI trial achieved an outcome of a mRS 2 in only 20% of the patients vs. 36% of the patients in the Multi MERCI trial, with a recanalization rate of 43% vs. 69.5% in the Multi MERCI trial ²¹. The Penumbra trial showed an

outcome of mRS 2 in only 29%, with a recanalization rate of 81.6%¹³. Castaño et al. described a successful revascularization of TICI 2b and 3 in 90% of the cases²². Compared to our results with respect to the small number of cases they are quite similar. One issue is important to note: in contrast to our data, Castaño et al. performed only mechanical thrombectomy in the anterior circle of Willis. This might have influenced the patients' outcome. Another interesting paper in the literature dealing with ischemic stroke and mechanical thrombectomy is the paper by Menon et al. who treated a comparable number of patients to ours and performed mechanical thrombectomy in the anterior and posterior circle of Willis. They reported a nearly 30% intracranial hemorrhage (ICH) rate after the procedure²³. We did not observe any ICH, but this may be due to the fact of a small number of patients. However, the most important factor is time. A mean time of 339 minutes like in the present study is too long. An overall procedure time (time from arriving at the angio ward, being prepared by the neu-

roanesthesiologist until the opening of the vessel by the neurointerventionalist) for mechanical thrombectomy of the anterior and posterior circle of Willis of 94 (+/- 53) minutes is a fact in this study. Time is brain; therefore all our efforts must focus on time. The best thrombectomy device whatever is not able to forgive a major failure in the organization of too slow transport of acute ischemic stroke patients to the specialized stroke center and the neurointerventionalists and neuroanesthesiologist must improve in their facilities every day.

The limitations of the present study are the small number of patients and the retrospective study design, but as we mentioned above, this is a early single center study. Discussing the functional outcome of the patients in this trial a further limitation of the study is the door to needle time.

In conclusion, withdrawal of fully recoverable intracranial stents shows encouraging results. However, further prospective large randomized trials are mandatory to confirm these early results.

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